

REMARKS/ARGUMENTS

The specification, Abstract, and claims have been amended to more clearly define the invention. The amendments simplify issues for appeal, render the claims allowable, and place the claims in better form for appeal. In addition, no new matter has been added by virtue of the amendments. Accordingly, applicants respectfully request entry of the amendments and reconsideration of the pending claims in light of the following remarks.

Pending Rejections

The substitute specification filed on December 4, 2002, is objected to under 35 U.S.C. §132 because it allegedly introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The Examiner contends the following is not supported by the original disclosure: (1) **paragraph 40** (“the convex surface 42 of the form cutter 29 of the Figs. 1 and 2 can not (sic) form a matting (sic) surface in the vertebral body that is complement (sic) to the concaval-convex shape of the endoprosthesis illustrated in Figures 4-6”); and (2) **paragraph 47** (“the drill head 20 described in Fig. 2 cannot form concaval-convex surfaces that mate with corresponding surfaces of an endoprosthesis described in figs. 4-6”) and (3) the **Abstract** (“it is not true that the cutter has a milling surface 22 having a width substantially the same as the width of the endoprosthesis in Figs. 6 and 7.”)

Paragraph 1 of the substitute specification is objected to for allegedly containing improper priority data.

The drawings are objected to under 37 C.F.R. § 1.83(a) as allegedly failing to show every feature of the invention specified in the claims. The Examiner contends that the “slot” recited in claims 29, 72, 86, 103 is not reflected in the drawings.

Claims 29, 36, 37, 39-50, 52-66, 72, 77, 78, 82, 86, 93-96, 98, 99, 103 and 110-125 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly is not described in the specification. The Action notes the following:

Claims 29, 72, 86 and 10, “a slot”;

Claim 37, “a smoother surface”;

Claims 49 and 62, “the milling surface has a width substantially the same as the width of the insert to be implanted”;

Claims 50, 53 and 63, “outwardly facing first and second milling surfaces”;

Claim 58, “said bearing surface is smooth”;

Claim 62, “the surface of that vertebra having a contour that substantially matches the contour of a surface of the insert to be implanted and that substantially matches the contour of the milling surface”;

Claims 36, 77, 93 and 110 “at least two milling surfaces ... and end plate”;

Claims 37, 78, 82 and 111 “a smooth surface”;

Claims 98, 112 and 113, “at least two milling surfaces”;

Claims 41, 47, 49, 62, 114, 120 and 121, “milling surface has a width selected to substantially match the overall width of the insert”; and

Claim 47, “at least one broad milling surface”.

Claims 1-3, 5-7, 13-50, 52-61 and 67-125 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,197,645 issued to Scheicher (hereinafter the “Scheicher patent” or “Scheicher reference”)¹.

RESPONSE

Applicants greatly appreciate the courtesies extended by the Examiner to Applicants and its representatives during a personal interview on March 23, 2004. Applicants’ representatives and the Examiner discussed the pending rejections and the Scheicher reference during the interview, and the undersigned believes that the interview served to advance prosecution of this case towards allowance of the pending claims.

At the outset, Applicants note two procedural requirements that appear to have been overlooked by the Office. first, on July 4, 2001, Applicants copied numerous claims from U.S. Patent No. 6,083,228, which had issued to Michelson on July 4, 2000 (the “Michelson ‘228 Patent”), and simultaneously filed a timely Request for Interference under 37 C.F.R. §1.607. These copied claims have been rejected over the prior art, but the Office Actions including these prior art rejections have not been signed by the Technology Center (T.C.) Director. Patent Office policy requires the approval of the T.C. Director before claims copied from an issued patent can be rejected under §102. *See*, M.P.E.P. §2307.02 (“If the ground of rejection is also applicable to the corresponding claims in the patent, any letter including the rejection must have

¹ The Scheicher reference discloses a drilling apparatus for the preparation of bone cavities and includes a plurality of drills that are simultaneously driven in opposite direction with the cutting surfaces of each drill overlapping the cutting surfaces of at least one other drill to provide intersecting bone cavities.

the approval of the T.C. Director.”) (emphasis added). The policy behind this requirement is manifest. If an Examiner were permitted to reject claims copied from a patent on prior art grounds, it is tantamount to a statement by the Office that a supposedly duly issued patent is invalid.²

Second, Applicants are concerned that the Patent Office has not handled this case with the requisite “special dispatch” mandated by 37 C.F.R. §1.607(b). Under Rule 607(b). “When an applicant seeks an interference with a patent, examination of the application, including any appeal to the Board, shall be conducted with special dispatch within the Patent and Trademark Office.” Going forward, therefore, applicants request expedited consideration of this Response and, if necessary, expedited consideration of any appeal.

NEW MATTER OBJECTIONS AND REJECTIONS

Applicants have canceled those portions of the substitute specification that the Office Action contends comprise new matter; namely, paragraphs 40 and 47 and the added language in the Abstract. Applicants have canceled the disputed language only because they believe the *original* specification supports the canceled subject matter, thus making the disputed paragraphs and language superfluous. Cancellation of the respective paragraphs and language from the

² When the point was brought to the Examiner’s attention in the interview her response was that she did not have to seek prior approval in light of the pending written descriptions rejections. She stated, however, that she would seek appropriate approval if and when the written description rejections are overcome. Applicant notes, however, that independent claim 25 is not alleged to lack written description support, yet it has been rejected under §102 as being anticipated by Scheicher, even though apparently no effort was made to obtain the requisite prior approval from the T.C. Director. Applicant respectfully requests that the record be clarified in this regard.

Abstract render moot these rejections. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the new matter objections and rejections.

REJECTIONS UNDER 35 U.S.C. § 112

As per the Agreement reached during the interview, Applicants have amended claims 36, 41, 47, 49, 50, 53, 62, 63, 77, 93, 98, 110, 112, 113, 114, 120, and 121 to overcome most of the pending written description rejections. For example, Applicants have replaced the phrase “a width selected to substantially match the overall width” of the insert with the phrase “a profile that mates with a profile” of the insert. This simply uses literal language of the application to convey the claimed concept. Applicants respectfully request that the corresponding rejections be withdrawn.

Applicants respectfully traverse the Examiner’s rejection that the “smooth surface” recited in claims 37, 58, 78, 82, and 111 lacks written description support. As pointed out by Applicants, the “smooth surface” recitation finds support, at the very least, in the originally filed drawings, which the Patent Office seems to dismiss. The Federal Circuit has unequivocally held that “drawings alone may provide a ‘written description’ of an invention as required by §112.” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1556 (Fed. Cir. 1991). “Thus, in those instances where a visual representation can flesh out words, as in the present application, drawings can and should be used like the written specification to provide evidence relevant to claim interpretation and used to interpret what the inventor(s) intended by the claim terms.” *Ex Parte Richard F. Bailey*, 2004 WL 696989, *3 (Bd. Pat. App. & Interf. 2004) (finding clear written description support in the figures); *see also Ex Parte Tamara M. Helming*, 2001 WL 816568, *2 (Bd. Pat. App. & Interf. 2001) (finding support in the original figures).

Applicants submit that the figures of the pending application comply with the above authorities. Indeed, the Examiner concedes that Figures 1-3 illustrate the surface of the housing as being “flat and smooth.” *See*, Final Office Action of August 22, 2003, ¶ 8. For written description purposes, the law requires nothing more. Applicants therefore respectfully request that the Examiner reconsider and withdraw these rejections

REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 1-3, 5-7, 13-50, 52-61 and 67-125 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the Scheicher patent. Applicants respectfully traverse this rejection because: (i) the Patent Office has not satisfied its burden under 35 U.S.C. § 102(b); and (ii) the Patent Office has failed to consider language in the pending claims that distinguishes the claims from the Scheicher patent. Additionally, as discussed previously, the rejection is improper *ab initio* as the Examiner has issued this rejection against copied claims without having obtained the requisite authorization to do so from the TC Director.

A. The Patent Office has not met its Burden under §102

Applicants respectfully submit that the Patent Office has failed to meet its burden in rejecting the pending claims under 35 U.S.C. §102. “A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, *every limitation of the claim.*” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). “The *identical invention* must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989). “Absence from the reference of *any* claimed element negates anticipation.” *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986).

Applicants submit there are numerous claim recitations that have not been addressed by the pending Final Office Action. For example, claim 33 recites a gear that “is configured to mate with corresponding teeth *on said cutter*.”³ The Office Action fails to address this claimed feature, much less indicate where the Scheicher reference teaches or suggests this feature. Similarly, claim 41 recites “at least one milling surface being configured and oriented such that it is generally parallel to the surface having a predetermined contour created on the end plate of the adjacent vertebral body when in use.” The Office Action does not specify what feature disclosed in Scheicher meets this claimed recitation.

Applicants respectfully submit that this anticipation rejection fails to accurately specify or identify those portions or features of Scheicher that purportedly anticipate the pending claim recitations. Although the Examiner makes general reference to the Scheicher reference, such general comments about the prior art are insufficient to support a rejection under 35 U.S.C. § 102(b). In addition, when asked in the interview to specifically indicate where the Scheicher reference teaches or suggests the claimed “milling surface,” the Examiner responded by saying “I don’t know,” and pointing to the Scheicher drawings as evidence of the type of milling the Scheicher device *could* perform on the adjacent vertebrae.⁴ At no time, however, has the

³ The referenced pinion gear 39 is not “on said cutter,” as recited in the claims.

⁴ The Office Action attempts to subsume the significance of the claimed invention by arguing that the dimensions of the drill head 5 -- which preferably comprise a maximum height of 2.6 - 6 mm (distances A, B, and C in Fig. 3, Col. 17, lines 52-57_ -- indicates that it could be used to “prepar[e] a space in a human spine to receive an insert if one desires to do so.” In effect, the Examiner says that a drill meant for drilling teeth could be used to perform spinal surgery. By this logic, any drill having a sufficiently small drill head would anticipate the claimed invention.

Examiner specifically indicate which portion of the Scheicher device *would* perform the milling. Whether a feature in a prior art reference *could* be used for a particular purpose is insufficient to support a rejection under 35 U.S.C. § 102(b) or 35 U.S.C. § 103, especially when an applicant is forced to speculate as to how the reference is being applied. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. *See e.g., Ex parte Gambogi*, 62 U.S.P.Q.2d 1209, 1212 (Bd.Pat.App & Interf. 2001) (“Rejection of claims in patent application...must be vacated and remanded, since patent examiner...has not referred to specific portions of...cited [reference], and since rejection therefore requires both applicants and Board of Patent Appeals and Interferences to speculate....”)

B. The Office Action has Improperly Dismissed Claim Language

Applicants believe that the pending claims patentably define over Scheicher even if the preamble is given no weight in construing the claim. Nonetheless, Applicants further respectfully submit that the Examiner has improperly refused to give weight to certain claim language, both in the preamble and in the body of the claims. The Federal Circuit has held that the preamble may limit the scope of a claim when, as here, the preamble contributes to the definition of the claimed invention. *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1350, 48 U.S.P.Q.2d 1225 (Fed. Cir. 1998). Indeed, where a term appears not only in the preamble, but is referenced in the body of the claim, that preamble and term may be found to be limiting. *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 689, 16 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1990); *see also Bell Comm. Research Inc. v. Vitalink Comm. Corp.*, 55 F.3d 615,

621,34 U.S.P.Q.2d 1816, 1820 (Fed. Cir. 1995) (the preamble can be incorporated by reference because of language appearing later in the claim, making it a limitation of the claim.)

Further, a preamble may be construed to be limiting based on its relationship to the description in the specification. *See, e.g., Applied Materials Inc. v. Advanced Semiconductor Materials*, 98 F.3d 1563, 40 U.S.P.Q.2d 1481 (Fed. Cir. 1996) (interpreting preamble recitation of “cold purge” to be limiting in light of the problem solved in the patent); *Bell Comm. Research Inc. v. Vitalink Comm. Corp.*, 55 F.3d at 621 (“Claim 6, as drafted and in light of the specification, is plainly limited such that it literally reads only on methods that transmit packets having both source and destination addresses”). In some cases, as here, the specification may make clear that the inventors were working on a *particular problem relevant to the preamble*, such that the preamble gives life and meaning to the claimed invention. *See General Electric Co. v. Nintendo Co.*, 179 F.3d 1350, 1361, 50 U.S.P.Q.2d 1910, 1919 (Fed. Cir. 1999).

Applicants respectfully submit that under the authority of the case law enumerated above, the preambles of the various pending claims **should** be considered in construing the claim. Taking the preamble of claim 25 as an example, the terms and phrases used therein indicate that the preamble is more than just language of intended use, as the Examiner asserts. Indeed, the preamble of claim 25 comprises language contributing to the definition of the claimed invention, and must thus be given weight. For instance, the expression “adjacent vertebral bodies,” which indicates the area within which the claimed invention is to be used to prepare a space, is further used in the body of the claim to specify exactly where the “at least one milling surface” is to create a surface contour. The Examiner cannot discard this limitation and apply the teachings of Scheicher (teaching a dental drill) to invalidate the pending claims.

Moreover, the specification makes clear that one of the problems overcome by the present invention is the inability of prior art tools and devices to effectively mill the surfaces of adjacent vertebrae. The Federal Circuit has clearly stated that the act of looking to the specification to determine whether a preamble has limiting effect is not only proper, but required:

No litmus test can be given with respect to when the introductory words of a claim, the preamble, constitute a statement of purpose for a device or are, in themselves, additional structural limitations of a claim.... The effect preamble language should be given can be resolved ***only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.***

General Electric Co. v. Nintendo Co., Ltd., 179 F.3d 1350, 1361 (Fed. Cir. 1999) (quoting *Corning Glass Works v. Sumitomo Elec. U.S.A.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989)).

In *General Electric Co. v. Nintendo Co., Ltd.*, the Federal Circuit, in determining whether the preamble would have limiting effect, considered the invention as ***described in the specification*** and stated as follows:

Here, the '125 specification makes clear that the inventors were working on the particular problem of displaying binary data on a raster scan display device and not general improvements to all display systems. ***In light of the specification, to read the claim indiscriminately to cover all types of display systems would be divorced from reality.*** The invention so described is restricted to those display devices that work by displaying bits, which is not true with respect to all display systems recited in just the body of the claim. "Thus, we conclude that the claim preamble in this instance does not merely state a purpose or intended use for the claimed structure. Rather, those words do give 'life and meaning' and provide further positive limitations to the invention claimed."

Id.

Applicants respectfully submit that the Patent Office must reach the same conclusion in this case. A review of the entire pending patent application reveals that the apparatus disclosed

and claimed must be able to fit within the area between two adjacent vertebrae and must be able to mill the adjacent surfaces thereof. *See e.g.*, Substitute Specification ¶ 12 (“It is an object of the instant invention to provide a drill head which can fit within the narrow space between two opposing vertebral bodies); ¶ 15 (“The instant invention overcomes the deficiencies of the prior art devices by providing a drill head with a narrow profile which can fit in the space between two opposing vertebral bodies.”) For the Examiner to ignore this critical distinction and to then broadly read the claims to cover any drilling device, in particular the dated dentist tool for drilling teeth described in Scheicher, in the words of the Federal Circuit, is to act “*divorced from reality.*” Accordingly, in view of the above authority, the respective preambles of the pending claims do give ‘life and meaning’ to the claimed inventions and thus provide further positive limitations to the invention claimed. Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

C. The Scheicher Device does not Necessarily Possess the Characteristics of the Claimed Invention

To the extent that the Examiner’s rejection is premised intentionally or otherwise on an inherency argument, Applicants submit the attached Expert Declaration of Mr. Carlos Gil to rebut the argument that the Scheicher device necessarily possesses the characteristics of the claimed invention. *See Exhibit A, Declaration of Mr. Carlos Gil.*⁶

Mr. Gil explains that the Scheicher device -- if used as the Office Action contends -- could not possibly be used to prepare a space in between adjacent vertebrae. In essence, the

⁶ Mr. Gil is qualified as at least one of ordinary skill in the art of the present application as evidenced by his educational and professional background.

rebut the argument that the Scheicher device necessarily possesses the characteristics of the claimed invention. *See* Exhibit A, Declaration of Mr. Carlos Gil.⁶

Mr. Gil explains that the Scheicher device -- if used as the Office Action contends -- could not possibly be used to prepare a space in between adjacent vertebrae. In essence, the Scheicher device could not be inserted into the area between adjacent vertebral bodies, and, if forced, could not be controlled to ensure the ability to create a surface contour in an adjacent vertebral body, and certainly could not be used to create at least one surface having a predetermined contour in an end plate of at least one adjacent vertebral body. When placed on the surface of a vertebral body, the tendency of the Scheicher device's drill head would be to roll off, much like a wheel does when coming in contact with a hard, solid surface. This lack of control essentially renders the Scheicher device a useless (if not dangerous) instrumentality for performing the type of spinal surgery contemplated by the claimed invention.

⁶ Mr. Gil is qualified as at least one of ordinary skill in the art of the present application as evidenced by his educational and professional background.

CONCLUSION

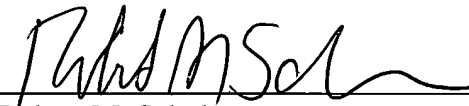
Since the cited reference, taken either singly or in combination with other references, fails to anticipate, teach or suggest the combinations set forth in the pending claims, and further fails to provide any motivation or suggestion of the desirability of modifying the structures or methods to arrive at the claimed combinations, Applicants submit that the pending claims are allowable over the cited reference. Accordingly, Applicants respectfully request that the Examiner withdraw his rejections, allow the pending claims and pass the application to issue.

If the Examiner believes that a telephone conference or interview would advance prosecution of this application in any manner, Applicants invite the Examiner to contact the undersigned at the telephone number listed below

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: April 22, 2004
Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W.
Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)


Robert M. Schulman
Registration No. 39,196